
Detect

Detect™ Hub User Manual

For in vitro diagnostic use.

For use with the Detect Covid-19 Test.

This product is for use under Emergency Use Authorization (EUA) only.

**REF 21101
MN-00005-US**

**Effective Date: November 2021
Rev A**

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This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.

This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.



Detect, Inc.
530 Old Whitfield St.
Guilford, CT 06437 USA
+1 (855) 322-3692
detect.com

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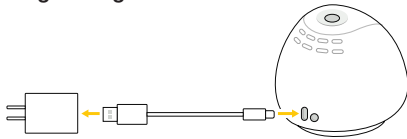
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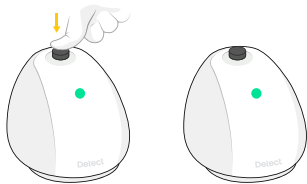
Using the Hub for the Detect Covid-19 Test

- 1.1 To start your test, you need a Detect Covid-19 Test (sold separately) and the Detect App (free to download). Follow the instructions in the app to prepare your sample using the Detect test. At the appropriate step, connect the Hub to a wall power outlet via the included USB-C cable and the USB power adapter. The Hub will beep when powered up, and it is ready to use when a solid green light is visible.



Caution: Do not insert the Test Tube into the Hub without powering up.

- 1.2 When ready, ensure that the Detect Cap on the Test Tube is securely tightened. Place the Test Tube in the Hub until you hear a beep. This indicates that the processing program has started.



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- 1.3 A blinking green LED light will indicate that the processing program is in progress.



- 1.4 A solid green LED light and two audible beeps will indicate completion of the process. This will take approximately 55 minutes.



- 1.5 Review the next steps in the Detect App before removing the Test Tube from the Hub.

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2 Product Information

2.1 Proprietary Name
Detect Hub

2.2 Established Product Name
Detect Hub

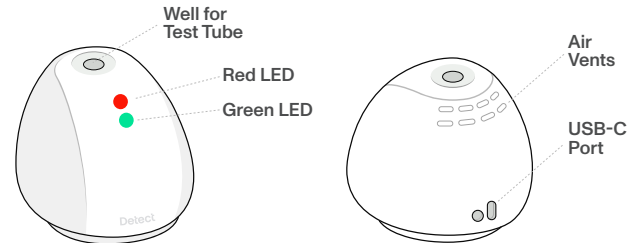
2.3 Intended Use
This Hub is intended for use in combination with the Detect Covid-19 Test for the purpose of detecting SARS-CoV-2 nucleic acids in human anterior nares specimens.

3 Hub Information

3.1 Hub Components
Each Detect Hub comes with the following components:

<u>Component Name</u>	<u>Quantity</u>
Detect Hub	1
USB-C Cable	1
USB Power Adapter	1
Model: S010WU0500200	
Input: 100-240V-50/60Hz 400mA	
Output: 5.0V=2000mA	
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3.2 Device Diagram



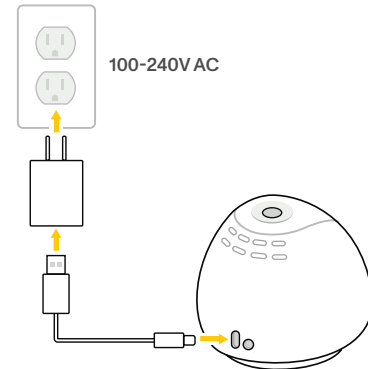
3.3 Hub Specifications

Model	21101
Input power	DC 5V==2A Max
Max. power	10 W
Operating environment	Indoor Use Only
Operating temperature range	59 °F - 86 °F (15 °C to 30 °C)
Storage temperature range	32 °F - 176 °F (0 °C to 80 °C)
Operating humidity range	25%–80%
Storage humidity range	0-80%
Max operating altitude	6500 ft (1981.2 m)
Dimensions (L×W×H)	4.3" x 3.4" x 2.6" (109 × 85 × 65 mm)
Net weight	3.3 oz (93 g)

3.4 Hub Installation

Only use the USB-C cable and USB power adapter included with this Detect Hub. Place the Hub on a level, horizontal surface in a dry place away from strong sunlight and with good ventilation around the device.

Attach the USB power adapter to the USB-C cable at the back of the Hub, and plug the other end of the power cord into an electrical outlet. The voltage requirement is 100-240V AC.



4 Hub Safety Precautions



Please read this manual carefully before using the device and follow all recommended safety precautions to avoid personal injury or damage to the device:

- Only use with the included adapter.
- Do not place anything besides Detect Test Tubes into the Hub.
- Do not open the Test Tube during or after the processing step in order to prevent Hub contamination with biohazardous substance.
- Keep the Hub dry, dust-free and with good ventilation on all sides. Do not place near a heat source.
- Unplug the Detect Hub before cleaning.
- Do not attempt to open or repair the Hub. Contact Detect Customer Support for any questions.
- Power off the Hub when not in use by unplugging from the wall outlet.
- If it will be left unused for an extended period of time, keep the device covered with a cloth to protect it from dust.

5 Cleaning & Maintenance



Power off the Hub before cleaning. Do not use corrosive cleaning liquids or fill the well with cleaning solutions.

Clean the plastic surface with cloth dampened with isopropyl alcohol. Do not clean the interior wall of the Hub well.

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Troubleshooting

PROBLEM

Hub does not power on (no LEDs are lit)


SOLUTION

Check the following connections:

- Hub and USB-C cable
- USB-C cable and A/C adapter
- A/C adapter to outlet

If problem persists, contact support.

Red LED fades in/out continuously



Cause: Hub is not receiving correct power. *Find the original A/C adapter that came with the Hub package and use it.*

Both Red and Green LED fade in/out continuously



Cause: Hub detects that its internal and/or external operating temperature is outside the specified range.

Relocate Hub to an environment where the temperature is 15 °C - 30 °C (59 °F - 86 °F). You may need to wait until Hub cools down to new temperature before it is operational again.

If the problem persists, please contact support at: support@detect.com +1 (855) 322-3692

PROBLEM

Red LED blinks continuously while Test Tube is inside Hub


SOLUTION

Cause: Test Tube placed in the Hub prior to the Hub being plugged in. Take out the tube and re-insert. If power was interrupted during processing, discard the test as it is no longer valid—start a new test.

Red LED blinks 5 times after Test Tube removal

Cause: Test Tube removed before processing step is complete. The test is no longer valid—do not proceed.

Solid Red LED




Cause: Hub detects internal error. *Contact support.*


Red LED blinks very rapidly, accompanied by a continuous series of beeps


Cause: Hub detects a severe internal error. *Remove Hub from power immediately. Contact support.*

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Legend of Symbols


 This symbol certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.


 This symbol indicates that the device has been tested to applicable standards by Underwriters Laboratory (UL).


 This symbol indicates direct current (DC) voltage.

 For In Vitro Diagnostics Use.


 This symbol indicates that caution is necessary when operating the device in order to avoid undesirable consequences. See Section 4 of this manual to see the full list of safety precautions.


 This symbol indicates the date on which the device was manufactured.


 This symbol identifies the manufacturer of the device.


 This symbol indicates that the instruction manual should be consulted.


 This symbol indicates that the device should be kept in dry conditions.

 This symbol indicates that the device is fragile and shall be handled with care.

 This symbol indicates that the device must not be used if the package holding the device is damaged.

 This symbol identifies the manufacturer's catalogue number.

 This symbol identifies the manufacturer's serial number.

 This symbol identifies that the electronics device meets the safety requirements specified for Class II equipment according to IEC 61140.

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Repeat Use

The Detect Hub is reusable and can be used with any additional Detect Tests.

However, if you need to dispose of it, please see the information below.

This electronics product contains substances which could damage the environment if not properly handled. As such, it is not possible to dispose of it in the regular trash.

Please check with your local government or electronics store to verify how to recycle your product. You can also check with your local electronics store to see if they will be able to recycle this product for you.

Depending on the solution chosen, fees may apply.

Detect

Contact support at:
support@detect.com
+1 (855) 322-3692